



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2009-0136; FRL-10023-41]

### **Pesticide Registration Review; Sulfuryl Fluoride Draft Interim Re-Entry Mitigation Measures and Registration Review Draft Risk Assessments for Sulfuryl Fluoride; Notice of Availability**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the availability of EPA's Sulfuryl Fluoride Draft Interim Re-Entry Mitigation Measures and several registration review draft risk assessments for sulfuryl fluoride. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, that the pesticide can perform its intended function without causing unreasonable adverse effects on human health or the environment. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment. EPA may pursue mitigation at any time during the registration review process if it finds that a pesticide poses unreasonable adverse effects to human health or the environment. To address human health incidents and in response to EPA's Office of Inspector General 2016 (OIG) Report, *Additional Measures Can Be Taken to Prevent Deaths and Serious Injuries From Residential Fumigations* (No. 17-P-0053), the EPA believes that the mitigation measures outlined in this Sulfuryl Fluoride Draft Interim Re-Entry Mitigation Measures are necessary to address identified human health risk concerns. The scope of this interim mitigation is focused on the use of sulfuryl fluoride as a structural fumigant in residential use sites. The Agency is also publishing several registration review risk assessments on sulfuryl fluoride for public comment.

**DATES:** Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit your comments by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, are available at <http://www.epa.gov/dockets>.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Public Reading Room are closed to visitors with limited exceptions. The EPA/DC staff continue to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For pesticide specific information contact:* Moana Appleyard, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (703) 308-8175; email address: [appleyard.moana@epa.gov](mailto:appleyard.moana@epa.gov).

*For general questions on the registration review program, contact:* Melanie Biscoe, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7106; email address: [biscoe.melanie@epa.gov](mailto:biscoe.melanie@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental and human health advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager listed under **FOR FURTHER INFORMATION**

#### **CONTACT.**

#### *B. What Should I Consider as I Prepare My Comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of

environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

## **II. Background**

Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed the Sulfuryl Fluoride Draft Interim Re-Entry Mitigation Measures. This decision document is in response to the EPA Office of the Inspector General's (OIG) 2016 report entitled *Additional Measures Can Be Taken to Prevent Deaths and Serious Injuries From Residential Fumigations* (available at:

[https://www.epa.gov/sites/production/files/2016-12/documents/\\_epaoig\\_20161212-17-p-0053.pdf](https://www.epa.gov/sites/production/files/2016-12/documents/_epaoig_20161212-17-p-0053.pdf)). The OIG conducted this report to determine the extent and nature of adverse impacts caused by structural fumigation, after two incidents in 2015, including one with the chemical sulfuryl fluoride. The OIG report sought to determine whether regulatory, program execution (e.g., training, funding, inspections, enforcement, etc.), or other factors were associated with adverse impacts. The focus of the audit with regards to the chemical sulfuryl fluoride, is residential fumigation use. The OIG report detailed several recommendations that fall under the purview of the Office of Pesticide Programs (OPP), including:

- Implement a process to evaluate label changes for all three brands of sulfuryl fluoride to require secured tenting and fumigation management plans.

- Clearly define the criteria for meeting the applicator stewardship training requirement.
- Conduct an assessment of clearance devices to validate their effectiveness.

The purpose of the Sulfuryl Fluoride Draft Interim Re-Entry Mitigation Measures is to propose risk mitigation measures to address these recommendations from the OIG report ahead of the typical mitigation phase of Registration Review. EPA expects that the implementation of the mitigation measures described in this risk mitigation document will allow sulfuryl fluoride products to remain available to users while addressing the recommendations from the OIG report.

The Agency has also completed several registration review draft human health and ecological risk assessments for sulfuryl fluoride. After reviewing comments received during the public comment period, EPA may then issue the Sulfuryl Fluoride Final Interim Re-Entry Mitigation Measures, revised risk assessments, explain any changes to the mitigation measures and draft risk assessments, and respond to comments. The Agency is only proposing mitigation to address the OIG audit at this time. Once all the risk assessments are completed for all the uses of sulfuryl fluoride, EPA may propose additional mitigation to address potential risks, as part of the normal registration review process. At that time, EPA may request public input on additional risk mitigation before completing a Proposed Interim Decision (PID). Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

### **III. Authority**

EPA is conducting its registration review of the sulfuryl fluoride documents listed in Unit IV pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of

pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

#### **IV. What Action is the Agency Taking?**

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's Sulfuryl Fluoride Draft Interim Re-Entry Mitigation Measures and several human health and ecological risk assessments for sulfuryl fluoride and opens a 60-day public comment period on the Sulfuryl Fluoride Draft Interim Re-Entry Mitigation Measures and the risk assessments. Additional support documents will be available in the public docket, which the Agency is not taking comment on.

#### **Documents to publish in response to the OIG audit and open for public comment:**

- Sulfuryl Fluoride Draft Interim Re-Entry Mitigation Measures.
- Sulfuryl Fluoride: Tier I Review of Human Incidents for Draft Risk Assessment.

#### **Support documents to publish in response to the OIG audit that are not open for public comment:**

- Memorandum: Assessment of Portable Devices for Their Effectiveness in Detecting Sulfuryl Fluoride (SF) at Clearance Level.
- Laboratory Testing of Portable Clearance Devices with Sulfuryl Fluoride Standard, Analytical Chemistry Branch (ACB), Office of Pesticide Programs.

The Agency is also publishing the following documents to the sulfur dioxide docket as part of the Registration Review of sulfur dioxide. These documents will be published for a 60-day comment period. After the dietary risk assessment for sulfur dioxide is completed and published for comment, the Agency will issue a Proposed Interim Decision (PID) to address all the uses of sulfur dioxide.

**Registration Review documents available for publication and open for public comment:**

- Sulfur Dioxide. Residential Post-application Exposure and Risk Assessment.
- Sulfur Dioxide. Occupational and Residential Exposure Assessment in Support of Registration Review.
- Sulfur Dioxide – Draft Risk Assessment in Support of Office of Registration Review Part I: Occupational and Residential Exposure.
- Six Structural and Commodity Fumigants: Combined Draft Risk Assessment (DRA) and Drinking Water Assessment (DWA) for Registration Review.
- Overview of Application Methods and Factors, Use, Usage, and Benefits of Commodity and Structural Fumigants: Phosphine [(066500) including Aluminum Phosphide (066501) and Magnesium Phosphide (066504)], Propylene Oxide (042501), Sulfur Dioxide (077601), Sodium Metabisulfite (111409), Sulfur Dioxide, (078003), Ethylene Oxide (042301), and Methyl Bromide (053201).

Pursuant to 40 CFR 155.53(c), EPA is providing an opportunity, through this notice of availability, for interested parties to provide comments and input concerning the Agency's Sulfur Dioxide Draft Interim Re-Entry Mitigation Measures and the draft human health and ecological risk assessments for sulfur dioxide. The Agency will

consider all comments received during the public comment period and make changes, as appropriate, to these documents. EPA may then issue the Sulfuryl Fluoride Final Interim Re-Entry Mitigation Measures, revised risk assessments, explain any changes to the mitigation measures and draft risk assessments, and respond to comments.

*Information submission requirements.* Anyone may submit data or information in response to this document. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements:

- To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted at a later date.
- The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audio-graphic or video-graphic record. Written material may be submitted in paper or electronic form.
- Submitters must clearly identify the source of any submitted data or information.
- Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.

**Authority:** 7 U.S.C. 136 *et seq.*



Dated: May 5, 2021.

**Mary Reaves,**

*Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.*  
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